

**IN THE CLAIMS:**

1. **(Currently amended)** A botanical drug or dietary supplement, for the treatment of or for use in patients with Hepatitis C infection, ~~comprising botanical raw materials, botanical drug substances or botanical ingredients consisting essentially of extracts from each of the following plant species sources:~~

- (a) ~~The the~~ fruit of *Silybum marianum*;
- (b) ~~The the~~ root of *Astragalus membranaceus* var *mongholicus* or *Hedysarum polybotrys*;
- (c) ~~The the~~ root of *Salvia miltiorrhiza*, *Salvia bowleyana* or *Salvia przewalskii*; and
- (d) ~~The the~~ fruit of *Schisandra chinensis* or *Schisandra sphenanthera*.

2. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 1 wherein each species is present in an amount, relative to the total weight of all ~~of the botanical raw materials, botanical drug substances or botanical ingredients extracts~~, as follows:

- (a) *Silybum* spp. from 22-48%;
- (b) *Astragalus* spp. or *Hedysarum* spp. from 20-63%;
- (c) *Salvia* spp. from 13-48%; and
- (d) *Schisandra* spp. from 2-19%.

3. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 2 wherein each species extract is present in an amount by weight percent as follows:

- (a) *Silybum* spp. from 30-40%;
- (b) *Astragalus* or *Hedysarum* spp. from 20-30%;
- (c) *Salvia* spp. from 20-30%; and
- (d) *Schisandra* spp. from 7.5-15%.

4. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 3 wherein each species extract is present in an amount by weight percent as follows:

- (a) *Silybum* spp. about 35%;
- (b) *Astragalus* or *Hedysarum* spp. about 26%;
- (c) *Salvia* spp. about 26%; and
- (d) *Schisandra* spp. about 11%.

5. **(Cancelled)**

6. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[5]] 1 further comprising including excipients.

7. **(Cancelled)**

8. **(Cancelled)**

9. **(Cancelled)**

10. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from the ~~the~~ Silybum spp. is standardised standardized against a marker of silybin.

11. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from the ~~the~~ Silybum spp. comprises at least 30% by weight silybin and isosilybin when calculated using HPLC.

12. **(Currently amended)** A botanical drug or dietary supplement as claimed in any of claim [[9]] 10 wherein the standardised standardized extract of the ~~the~~ Silybum spp. is a brownish yellow powder which is or has:

- (i) no less than 30% silybin by HPLC;
- (ii) no more than 0.5% soluble in pentane;
- (iii) a sulphated ash content of no more than 1% by weight;
- (iv) a heavy metal content of no more than 100ppm;
- (v) a residual organic solvent content of no more than 1% ethanol, no more than 0.01% ethyl acetate and no more than 0.01% hexane by weight;
- (vi) a bacterial content of no more than 1000 cfu/g; and
- (vii) a fungal content of no more than 100cfu/g.

13. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from the ~~the~~ Astragalus spp. is standardised against a marker of Astragaloside IV.

14. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~botanical drug substance~~ extract from the *Astragalus* spp. comprises at least 0.4% by weight Astragaloside IV when calculated using HPLC.

15. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~botanical drug substance~~ extract from the *Astragalus* spp. has a TLC chromatographic fingerprint substantially as illustrated in Fig 1 or a HPLC fingerprint substantially as illustrated in Fig 4.

16. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~standardised~~ standardized extract of *Astragalus* spp. is a pale yellow powder which ~~is~~ or has:

- (i) no less than 0.4% Astragaloside IV by weight;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

17. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from the *Salvia* spp. is standardised against a marker of Tanshinone II A.

18. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~botanical drug substance~~ extract from the *Salvia* spp. comprises at least 1.5% by weight of Tanshinone IIA as calculated using HPLC.

19. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~botanical drug substance~~ extract from the *Salvia* spp. has a TLC chromatographic fingerprint substantially as illustrated in Fig 2 or a HPLC fingerprint substantially as illustrated in Fig 6.

20. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~standardised~~ standardized extract of the *Salvia* spp. is a dark red powder which ~~is~~ or has:

- (i) no less than 1.5% by weight Tanshinone IIA by HPLC;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

21. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein ~~botanical drug substance~~ the extract from ~~the~~ *Schisandra* spp. is standardised standardized against a marker of Schizandrol A.

22. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 21 wherein the ~~botanical drug substance~~ extract from ~~the~~ *Schisandra* spp. comprises at least 2.0% by weight Schizandrol A using HPLC.

23. **(Currently amended)** A botanical drug substance, or dietary supplement as claimed in claim 21 wherein the ~~botanical drug substance~~ extract from ~~the~~ *Schisandra* spp. has a TLC chromatographic fingerprint substantially as illustrated in Fig 3 or a HPLC fingerprint substantially as illustrated in Fig 8.

24. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 22 wherein the standardised standardized extract of *Schisandra* spp. is a brownish red powder which ~~is~~ ~~or~~ has:

- (i) no less than 2.0 % by weight Schizandrol A;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

25. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein ~~the standardised~~ each extract is a dried ethanolic extract.

26. **(Cancelled)**

27. **(Cancelled)**

28. **(Cancelled)**

29. **(Cancelled)**

30. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 which is provided in a unit dosage form.

31. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 which is wherein the extracts are a suspension powder mixture.

32. **(Currently amended)** A botanical drug or dietary supplement as claimed in claims 34 claim 1 further comprising including as excipients:

(a) at least one or more gellants gellant or thickeners thickener comprising at least one xanthum gum having a particle size distribution such that 100% by weight of the particles pass a 60 mesh sieve, 95% by weight of the particles pass a 80 mesh sieve and 70% by weight of the particles pass a 200 mesh sieve,

(b) at least one or more fillers filler; and

(c) at least one or more wetting agents agent and or surfactants surfactant.

33. **(Currently amended)** A botanical drug or dietary supplement as claimed in claims claim 32 wherein the xanthan gum has a molecular weight of from  $3.5 \times 10^6$  to  $4.0 \times 10^6$ .

34. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 32 wherein the wetting agent is a polyethylene glycol or macrogol.

35. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 further comprising including one or more of a disintegrating agent, a lubricant, a sweetening agent, a flavouring agent and a viscosifying agent.

36. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 which is wherein the extracts are packaged in a sachet.

37. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 which is packaged with a dispensing container.

38. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 37 wherein the dispensing container has a sealable lid.

39. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 comprising wherein said extracts are botanical drug substances in [[a]] the following unit dose doses:

- (i) 0.200g to 0.250g of a botanical drug substance from [[a]] *Silybum* spp.;
- (ii) 0.585g to 1.95g of a botanical drug substance from [[a]] *Astragalus* spp.;
- (iii) 0.225g to 0.375g of a botanical drug substance from [[a]] *Salvia* spp.; and
- (iv) 0.150g to 0.600g of a botanical drug substance from [[a]] *Schisandra* spp..

40. **(Currently amended)** A method of treating a patient to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function comprising administering to a patient an efficacious dosage of [[a]] the botanical drug or dietary supplement as claimed in claim 1.

41. **(Currently amended)** The use of a botanical drug or dietary supplement to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function, comprising administrating to a patient an efficacious dosage of the botanical drug or dietary supplement as claimed in claim 1 in combination with another drug, said another drug being present in an amount efficacious to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function.

42. **(Currently amended)** The use as claimed in claim 41 wherein the another drug is interferon.

43. **(Cancelled)**

44. **(Cancelled)**

45. **(Cancelled)**

46. **(Cancelled)**

47. (Cancelled)

48. (Cancelled)

49. (Cancelled)